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| APPLICATION NO.   | FILING DATE           | FIRST NAMED INVENTOR                   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------------|--|---------------------|------------------|
| 10/749,773  | 12/30/2003            | Sandra J. Regnell                      | 015916-299          | 1067             |
| 21836 7590 04/04/2007<br>HENRICKS SLAVIN AND HOLMES LLP<br>SUITE 200<br>840 APOLLO STREET<br>EL SEGUNDO, CA 90245 |                       |  | EXAMINER            |                  |
|   |                       |  | · NGUYEN, TUAN VAN  |                  |
|   |                       |  | ART UNIT            | PAPER NUMBER     |
|   | •                     |  | 3731                |                  |
| SHORTENED STATUTOR  | RY PERIOD OF RESPONSE | DD OF RESPONSE MAIL DATE DELIVERY MODE |                     | Y MODE           |
| 31 🗆  | DAYS                  | 04/04/2007                             | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  | Application No.   | Applicant(s)   |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
|  | 10/749,773  | REGNELL ET AL.   |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |  |
|  | Tuan V. Nguyen  | 3731   |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | pears on the cover sheet with the c   | orrespondence address  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D.  Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period or Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE  | I. sely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |  |
| Status   |   |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on   |   |  |  |  |  |  |  |
| ,  | action is non-final.  |  |  |  |  |  |  |
| 3) Since this application is in condition for allowa   |   | secution as to the merits is   |  |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-74</u> is/are pending in the application.  |   |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |  |  |  |  |  |
| 6) Claim(s) is/are rejected.   |   |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  | · · · · · · · · · · · · · · · · · · ·   |  |  |  |  |  |  |
| 8) Claim(s) 1-74 are subject to restriction and/or   | election requirement.   |  |  |  |  |  |  |
| Application Papers ·   |   |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |   |  |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |   |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |  |  |  |  |  |
| a) All b) Some * c) None of:   |   |  |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |  |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |   |  |  |  |  |  |  |
| oce the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |  |
|  |   |  |  |  |  |  |  |
| Attachment(s)  | ٠ ١٠٠٠ المالية ال | (PTO 413)  |  |  |  |  |  |
| 1)   | 4) Interview Summary Paper No(s)/Mail Da  |  |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application   |   |  |  |  |  |  |  |
| Paper No(s)/Mail Date 6)  Other:   |   |  |  |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-50 and 68-74, drawn to a needle assembly, classified in class
     606, subclass 185
  - II. Claims 51-67, drawn to method of assembling a needle assembly, classified in class 604 subclass 523.
- 2. The inventions are distinct, each from the other because of the following reasons:

  Inventions II and I are related as process and apparatus for its practice. The

  inventions are distinct if it can be shown that either: (1) the process as claimed

  can be practiced by another materially different apparatus or by hand, or (2) the

  apparatus as claimed can be used to practice another and materially different

  process (MPEP § 806.05(e)). In this case the assembly process as claimed can

  be practiced by another and materially different apparatus such as assembling a

  therapeutic balloon catheter assembly wherein the catheter is use for carrying

  and deploying at least one needle for delivery of drug.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- Due to the complexity of this requirement, no solicitation of an oral election was made. This requirement is being sent out by mail only.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen March 30, 2007

M/ Hayer\_

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER